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510(k) Summary K003833

Submitter Information:

Igel Vision Care Pte Ltd
c/o Szabocsik & Associates
203 North Wabash Avenue, Suite 1200
Chicago, IL 60601

Contact Person: John M. Szabocsik, PH.D.
Official Correspondent

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Date Prepared: January 10, 2001

Device Name:

Common Name: Soft (hydrophilic) Contact Lens

Trade/Proprietary Names: Igel® 55 Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (blue visibility tinted)

Igel® 55 (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (blue visibility tinted).

Classification Name: Soft (hydrophilic) Contact Lens

Device Classification: Class II (21 CFR 886.5925)

Predicate Devices:

The Specialty Progressive (methafilcon A) Soft (hydrophilic) Multifocal Contact Lens and the Specialty Choice AB (methafilcon A) Soft Single Vision Contact Lens were selected as the predicate devices. These devices, which were cleared under 510(k) K963488, are manufactured from the same polymer, using the same manufacturing process, and the same lens designs.

Description of Devices:

The Igel® 55 Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (blue visibility tinted) and the Igel® 55 (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (blue visibility tinted) are hemispherical flexible shells which cover the cornea and a portion of the adjacent sclera. The Igel® 55 Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens is available as an aspherical multifocal lens and the Igel® 55 (methafilcon A) Soft (hydrophilic) Single Vision Contact Lens is available as a single vision lens.

The lens material (methafilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid cross-linked with ethyleneglycol dimethacrylate (45.0%) and water (55.0%). The Igel® 55 Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear and the Igel® 55 (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear are tinted using Vat Blue #6 in an in-monomer tinting process.

Comparison to Predicate Device

PARAMETER	Igel® 55 Multifocal & Igel® 55 hydrophilic Contact Lenses for Daily Wear	Progressive & Choice AB hydrophilic Contact Lenses for Daily Wear
Material	methafilcon A	methafilcon A
Material classification	hydrophilic Lens Group 4	hydrophilic Lens Group 4
Indication for use	myopia, hyperopia, and presbyopia	myopia, hyperopia, and presbyopia
Water content	55%	55%
Light transmittance	98%	90 to 97%, dependent upon tint
Dk (35°C)	18.8×10^{-11}	19.7×10^{-11}
Powers	+20.00 to -20.00 Diopters	+20.00 to -20.00 Diopters
Color	blue visibility	blue visibility
Refractive index	1.42	1.41
Specific gravity	1.06	1.06
Method of manufacture	Molded	Molded
Tint process	In-Monomer Tinted	Vat Dyed

Indications for Use:

The Igel® 55 Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (blue visibility tinted) is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The Igel® 55 (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (blue visibility tinted) is indicated for daily wear for the correction of refractive ametropia (myopia, and hyperopia) in persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The lenses may be disinfected using a chemical or hydrogen peroxide disinfection system. Eyecare practitioners may prescribe the lenses for daily wear and/or frequent replacement.

Description of Safety and Substantial Equivalence:

A series of preclinical tests were performed to demonstrate substantial equivalence of the Igel® 55 Multifocal and Igel® 55 (methafilcon A) Contact Lenses for Daily Wear. Results of this testing support the equivalence of the devices to the predicate devices from microbiological, physicochemical and manufacturing perspectives.

Conclusion:

Information submitted in the 510(k) establishes that the Igel® 55 Multifocal and Igel® 55 Single Vision Contact Lenses (methafilcon A) have comparable physicochemical properties to the predicate devices and do not raise questions of safety and effectiveness. Therefore, the devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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John M. Szabocsik, Ph.D.
Official Correspondent
Igel Vision Care PTE Ltd.
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203 North Wabash Avenue, Suite 1200
Chicago, IL 60601

Re: K003833
Trade Name: Igel® 55 Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (blue visibility tinted)
Igel® 55 (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (blue visibility tinted)
Regulatory Class: II
Product Code: 86 LPL
Dated: December 8, 2000
Received: December 11, 2000

Dear Dr. Szabocsik:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE

510(k) NUMBER (IF KNOWN) K003833

DEVICE NAMES

Igel® 55 Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (blue visibility tinted)
and
Igel® 55 (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (blue visibility tinted)

INDICATIONS FOR USE

The Igel® 55 Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (blue visibility tinted) is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The Igel® 55 (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (blue visibility tinted) is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The lenses may be disinfected using a chemical or hydrogen peroxide disinfection system. Eyecare practitioners may prescribe the lenses for daily wear and/or frequent replacement.

Prescription Use ✓
(Per 21 CFR 801.109)

JS

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003833